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10/647,796	08/26/2003	Zeev Glozman	32965	2006

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EXAMINER	
DAY, HERNG DER	

ART UNIT	PAPER NUMBER
2128	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,796	GLOZMAN ET AL.	
	Examiner	Art Unit	
	HERNG-DER DAY	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-39 and 41-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-39 and 41-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to Applicants' Response ("Response") to Office Action dated November 24, 2008, filed May 26, 2008.

1-1. Claims 1, 14, and 23 have been amended. Claims 1-16, 18-39, and 41-49 are pending.

1-2. Claims 1-16, 18-39, and 41-49 have been examined and rejected.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16, 18-22, 46, 47, and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3-1. Claim 1 recites the limitation "said bones" in line 11 of the claim. There is insufficient antecedent basis for this limitation in the claim.

3-2. Claims not specifically rejected above are rejected as being dependent on a rejected claim.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-16, 18-22, 46, 47, and 49 are rejected under 35 U.S.C. 101 because the inventions as disclosed in claims are directed to non-statutory subject matter.

5-1. Claims 1-16, 18-22, 46, 47, and 49 are improper method claims because they have not been tied to any other statutory class (e.g., a *particular* apparatus) that may be used in a limitation, not merely in the preamble, to accomplish the method steps. Accordingly, claims 1-16, 18-22, 46, 47, and 49 are not patent eligible processes and are rejected as being directed to non-statutory subject matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-16, 18-39, and 41-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause et al., U.S. Patent 6,711,432 B1 issued March 23, 2004 and filed October 23, 2000, in view of Kenet et al., U.S. Patent 5,016,173 issued May 14, 1991.

7-1. Regarding claim 1, Krause et al. disclose a method for preoperative planning and simulating of an orthopedic surgical procedure to be performed on an anatomical structure, using medical images of the anatomical structure, comprising inter alia:

[[a. providing a real dimension unit defining a length, to appear in an image with said anatomical structure for providing calibration of the imaged anatomical structure;]]

b. obtaining and displaying the medical images of the anatomical structure [[along with said real dimension unit]] prior to said orthopedic surgical procedure[[, and using said real dimension unit calibration determining an extent of trauma present in said bones]] (X-ray or fluoroscopic images of a patient's bone, column 6, lines 18-20; several regular X-ray images of the patient (which are typically taken before any surgery), column 6, lines 42-51);

c. segmenting the anatomical structure into segments in said medical images prior to said orthopedic surgical procedure, said segments being in an original arrangement (Segmentation, column 6, lines 52-57; segmented at regular intervals 120 throughout the 3D model, column 9, lines 14-22; FIG. 6A shows that the same 20 virtual slices 142 are taken as in the single osteotomy procedure, column 9, lines 53-54), the anatomical structure comprising bones and the segmentation comprising segmentation of the bone to form independently movable bone part segments to represent trauma present in said bones (The present invention may be used in cases of multiple trauma with long bone fractures. … apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40); and

d. using the obtained medical images comprising said [[calibrated]] imaged anatomical structure, planning a result of the orthopedic surgical procedure to be performed on the anatomical structure to reduce said trauma present in said bone (Figures 4-6; apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40), by rearranging of said image anatomical structure segments from said original arrangement to simulate said result within said anatomical structure (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, line 14, through column 10, line 7) so that [[calibrated]] output

images comprising said bone segments rearranged to reduce said trauma are produced (the planning software preferably plots the results on a 3D diagram, column 10, lines 8-17).

Krause et al. fail to expressly disclose: (1) a. providing a real dimension unit defining a length, to appear in an image with said anatomical structure for providing calibration of the imaged anatomical structure; and (2) and using said real dimension unit calibration determining an extent of trauma present in said bones.

Kenet et al. disclose, "Once an image has been captured, calibration 314 of the image is performed to calibrate for *absolute distances* and to correct for spatial, color, or intensity distortions due to the acquisition equipment and circumstances. … For example, an image of a ruler or grid may be obtained during a calibration session, or simultaneously with the image of the surface structure of interest." (Kenet, column 10, lines 40-51). In other word, associated with an image of a ruler in it, the image of interest becomes a *calibrated image* and is calibrated for *absolute distances*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Krause et al. to incorporate the teachings of Kenet et al. because as suggested by Kenet et al., an image of a ruler obtained simultaneously with the image of the surface structure of interest would calibrate for absolute distances and to correct for spatial distortions due to the acquisition equipment and circumstances.

7-2. Regarding claim 2, Krause et al. further disclose comprising dynamic rendering of medical device from pre defined members, the method allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, lines 25-28).

7-3. Regarding claim 3, Krause et al. further disclose wherein said medical images are X-ray images (regular X-ray images, column 6, lines 42-51).

7-4. Regarding claim 4, Krause et al. further disclose wherein said medical images are a combination of plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

7-5. Regarding claim 5, Krause et al. further disclose wherein said medical images comprise a plurality of views of said anatomical structure (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

7-6. Regarding claim 6, Krause et al. further disclose wherein the obtaining step comprises transforming of said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

7-7. Regarding claim 7, Krause et al. further disclose wherein said obtaining includes composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

7-8. Regarding claim 8, Krause et al. further disclose wherein the obtaining step comprises calibrating of images (An additional level of free-form deformation may be added for additional accuracy, column 7, lines 45-51).

7-9. Regarding claim 9, Krause et al. further disclose wherein said calibrating comprises registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

7-10. Regarding claim 10, Krause et al. further disclose wherein said calibrating comprises dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

7-11. Regarding claim 11, Krause et al. further disclose wherein said calibrating comprises image enhancements comprising brightness and contrast adjustments, and edge detection (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

7-12. Regarding claim 12, Krause et al. further disclose wherein the segmenting step is performed in at least one of a group of ways, comprising: manual performance by a medical expert, automatic performance, wherein the anatomical structure segments are segmented according to predefined rules, and semi-automatic performance, wherein the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

7-13. Regarding claim 13, Krause et al. further disclose wherein said rearranging comprises simulating different positioning of said image anatomical structure segments (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, lines 23-67).

7-14. Regarding claim 14, Krause et al. further disclose wherein said different positioning of said image anatomical structure segments relates to reducing of said trauma during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

7-15. Regarding claim 15, Krause et al. further disclose wherein said different positioning of said image anatomical structure segments relates to pre designed osteotomy treatments (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

7-16. Regarding claim 16, Krause et al. further disclose comprising inserting implants, in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, lines 25-28).

7-17. Regarding claim 18, Krause et al. further disclose comprising a step of choosing a plurality of fixation elements from a predefined database (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

7-18. Regarding claim 19, Krause et al. further disclose comprising rules for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

7-19. Regarding claim 20, Krause et al. further disclose wherein said planning comprises producing and storing the output images and planning reports of a plurality of alternatives of said steps of segmenting and planning, for the purpose that the best alternative for medical treatment is selected from said alternatives; said planning report comprising part definition of said calibrated artificial elements selected for the treatment as well as patient information (determine the appropriate locations, column 10, lines 8-17); said planning report comprising part definition of calibrated artificial elements selected for the treatment as well as patient information (preliminary surgical plan, column 10, lines 46-62).

7-20. Regarding claim 21, Krause et al. further disclose additionally comprising a step of providing hard copies of said output images and said planning reports of a selected set of said alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

7-21. Regarding claim 22, Krause et al. further disclose additionally comprising a step of communicating said output images and said planning reports to a plurality of remote users (to remotely access other experts, column 2, lines 48-58).

7-22. Regarding claim 23, Krause et al. disclose an apparatus for pre planning and simulating of an orthopedic surgical procedure to be performed on an anatomical structure, using medical images of the anatomical structure, the apparatus comprising;

[[a. a real dimension unit defining a length, to appear in an image with said anatomical structure for providing calibration of the imaged anatomical structure;]]

b. segmenting means for defining and marking anatomical structure segments in an original arrangement in the medical images of the anatomical structure (Segmentation, column 6, lines 52-57; segmented at regular intervals 120 throughout the 3D model, column 9, lines 14-22; FIG. 6A shows that the same 20 virtual slices 142 are taken as in the single osteotomy procedure, column 9, lines 53-54), the anatomical structure comprising bones and the segments being segments of said bones independently movable to be representative of trauma present in said bones (The present invention may be used in cases of multiple trauma with long bone fractures. … apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40);

c. planning means for planning a result of said orthopedic surgical procedure to be performed on the anatomical structure to minimize said trauma, using the [[calibrated]] medical images of the anatomical structure [[and said real dimension unit calibration to estimate an extent of said trauma]] (Figures 4-6; apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40), the planning means comprising means for rearranging of said image anatomical structure segments from said original arrangement to simulate said

result within said anatomical structure (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, line 14, through column 10, line 7) thereby to produce [[calibrated]] output images comprising said rearranged bone segments (the planning software preferably plots the results on a 3D diagram, column 10, lines 8-17);

d. a memory for storing said medical images and a desired result (a planning computer … has developed a detailed preliminary surgical plan, column 11, lines 15-19); and,

e. a display for displaying said [[calibrated]] medical images and said output images (The surgeon can preferably view the 3D computer simulation or other plan of the surgery, column 11, lines 19-27).

Krause et al. fail to expressly disclose: (1) a. a real dimension unit defining a length, to appear in an image with said anatomical structure for providing calibration of the imaged anatomical structure; and (2) using … said real dimension unit calibration to estimate an extent of said trauma.

Kenet et al. disclose, "Once an image has been captured, calibration 314 of the image is performed to calibrate for *absolute distances* and to correct for spatial, color, or intensity distortions due to the acquisition equipment and circumstances. … For example, an image of a ruler or grid may be obtained during a calibration session, or simultaneously with the image of the surface structure of interest." (Kenet, column 10, lines 40-51). In other word, associated with an image of a ruler in it, the image of interest becomes a *calibrated image* and is calibrated for *absolute distances*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Krause et al. to incorporate the teachings of Kenet et al. because as suggested by Kenet et al., an image of a ruler obtained simultaneously with the image of the surface structure of interest would calibrate for absolute distances and to correct for spatial distortions due to the acquisition equipment and circumstances.

7-23. Regarding claim 24, Krause et al. further disclose comprising means for dynamic rendering of medical device from pre defined members, allowing dynamic rendering of medical devices with a pre defined relationship, wherein two or more members can be integrated to one member in runtime according to a predefined rule (multifunctional markers 110, column 10, lines 25-28).

7-24. Regarding claim 25, Krause et al. further disclose wherein the medical images are X-ray images (regular X-ray images, column 6, lines 42-51).

7-25. Regarding claim 26, Krause et al. further disclose wherein the medical images are combination of a plurality of imaging techniques (fusing selective volumetric MRI/CAT scan data, column 8, lines 4-14).

7-26. Regarding claim 27, Krause et al. further disclose wherein the medical images comprise a plurality of views of the same anatomical structures (a series of two-dimension representations of the patient's bone, column 6, lines 42-51).

7-27. Regarding claim 28, Krause et al. further disclose additionally comprising means for transforming said medical images to digital images (until the projections of the 3D bone model 84, 86 match the X-ray or other images 83 of the patient's bone, column 7, lines 21-44).

7-28. Regarding claim 29, Krause et al. further disclose additionally comprising means for composing of several images of the same anatomical structure into a full-length view of said anatomical structure (use several regular X-ray images of the patient, column 6, lines 42-51).

7-29. Regarding claim 30, Krause et al. further disclose additionally comprising calibration means for images (An additional level of free-form deformation may be added for additional accuracy, column 7, lines 45-51).

7-30. Regarding claim 31, Krause et al. further disclose wherein the calibration means are also utilized for registration of different views (to more closely match the two-dimensional segmented bone images, column 7, lines 9-17).

7-31. Regarding claim 32, Krause et al. further disclose wherein the calibration means are also utilized for dimension and orientation calibration (the 3D template bone model 88 is reshaped to resemble the patient's actual bone 82, column 7, lines 9-17).

7-32. Regarding claim 33, Krause et al. further disclose wherein the calibration means are also utilized for image enhancements (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

7-33. Regarding claim 34, Krause et al. further disclose wherein the calibration means are also utilized for correction of image distortions (The software then determines how the template bone model should be altered to more accurately depict the patient's actual misaligned bone, column 7, lines 5-8).

7-34. Regarding claim 35, Krause et al. further disclose wherein the segmenting means are manually operated by a medical expert or wherein the segmenting means are automatically operated according to predefined rules, or wherein the segmenting means are operated semi-

automatically in the manner that the segmenting step is performed automatically with the assistance of a medical expert (Segmentation may be accomplished using a light board and digitizing stylus, column 6, lines 54-57).

7-35. Regarding claim 36, Krause et al. further disclose wherein the planning means are additionally utilized for simulating different positioning of said anatomical structure segments (the planning software preferably goes through all possible iterations of osteotomy locations. With a single osteotomy and 20 slices 142, there are 20 iterations. With a double osteotomy and 20 slices, there are just under 200 unique iterations, column 9, lines 23-67).

7-36. Regarding claim 37, Krause et al. further disclose wherein the planning means are utilized for simulating reduction of fractures during trauma treatment (apply the present system to obtain an exact realignment of the fractured bone, column 17, lines 34-40).

7-37. Regarding claim 38, Krause et al. further disclose wherein said different positioning of said anatomical structure segments relates to pre designed osteotomy treatments for deformed anatomical structures (determine the appropriate locations for the double osteotomy or other multiple orthopedic procedures, column 10, lines 8-17).

7-38. Regarding claim 39, Krause et al. further disclose comprising implants, for superposition in the manner that superposition of implants and said segmented anatomical structure over non-segmented fragments of said anatomical structure is provided (multifunctional markers 110, column 10, lines 25-28).

7-39. Regarding claim 41, Krause et al. further disclose comprising a predefined database comprising predefined sets of fixation elements (the guides and markers 110 have already been modeled by the planning computer, column 10, lines 34-42).

7-40. Regarding claim 42, Krause et al. further disclose comprising means for correct positioning of said fixation elements so incorrect positioning of said fixation elements is prevented (determine the appropriate locations, column 10, lines 8-17).

7-41. Regarding claim 43, Krause et al. further disclose additionally comprising a means for producing and storing planning reports of plurality of alternatives, for the purpose that the best alternative for medical treatment is selected from said alternatives (determine the appropriate locations, column 10, lines 8-17), said planning reports comprising part definition of calibrated artificial elements selected for the medical treatment and patient information (preliminary surgical plan, column 10, lines 46-62).

7-42. Regarding claim 44, Krause et al. further disclose additionally comprising a hard copy producer configured to produce hard copies of said output images and said planning reports of a selected set of said alternatives (The surgical plan may be sent to the surgeon using various media types, column 11, lines 19-27).

7-43. Regarding claim 45, Krause et al. further disclose additionally comprising a communication device for communicating said output images and said planning reports to remote users (to remotely access other experts, column 2, lines 48-58).

7-44. Regarding claim 46, Kenet et al. further disclose wherein said real dimension unit comprises an object of a known length (an image of a ruler … may be obtained … simultaneously with the image of the surface structure of interest, column 10, lines 49-51).

7-45. Regarding claim 47, Krause et al. further disclose wherein said medical images of the anatomical structure are imaged on an imager remote from the location of the orthopedic surgical procedure (several regular X-ray images of the patient (which are typically taken before any surgery), column 6, lines 42-51).

7-46. Regarding claim 48, Krause et al. further disclose wherein said displayed image comprises a final image for the orthopedic surgical procedure (a planning computer … has developed a detailed preliminary surgical plan, … The surgical plan may be sent to the surgeon using various media types including: still images and illustrations, column 11, lines 15-25).

7-47. Regarding claim 49, Krause et al. further disclose wherein said obtained output images further comprise, at least one feature selected from the group consisting of: a plurality of calibrated organs; a plurality of calibrated artificial elements; and at least one superposition of said calibrated artificial elements on said calibrated organs or organ segments (Figure 4).

Applicants' Arguments

8. Applicants argue the following:

8-1. Claim Rejections - 35 U.S.C. §101

(1) "Claim 1 has therefore been amended to tie it to an imaging apparatus. It is believed that the rejection is thereby overcome." (Page 10, paragraph 3, Response)

8-2. Claim Rejections - 35 U.S.C. §112

(2) "Claim 14 has been amended to make the terminology consistent with claim 1." (Page 10, paragraph 4, Response)

8-3. Claim Rejections - 35 U.S.C. 103

(3) "This is because only Kenet teaches a fixed dimension unit and neither Kenet nor Krause actually image fractures. All Kenet teaches is using a fixed dimension unit to give a scale to a visually accessible surface. But fractures are not visually accessible, and are not even imaged by Krause to make them artificially visually accessible. It therefore makes no sense to

photograph a visual fixed dimension unit to give a scale to a fracture that cannot be seen." (Page 10, the last paragraph, through page 11, paragraph 1, Response)

(4) "The same amendment referred to above in respect of claim 1 have been made to claim 23, which is now believed to be allowable for the same reason." (Page 11, paragraph 5, Response)

(5) "The remaining claims are believed to be allowable as being dependent on either one of claims 1 and 23." (Page 11, paragraph 6, Response)

Response to Arguments

9. Applicants' arguments have been fully considered.

9-1. Applicants' argument (1) is not persuasive. To qualify as a §101 statutory process, the claim should positively recite any other statutory class to which it is tied or positively recite the subject matter that is being transformed. An imaging apparatus recited merely in the preamble and not in a limitation may not be considered as positively recited.

9-2. Applicants' argument (2) is persuasive. The rejections of claim 14 under 35 U.S.C. 112, second paragraph, in Office Action dated November 24, 2008, have been withdrawn.

9-3. Applicants' arguments (3)-(5) are not persuasive. Specifically, Krause et al. disclose at column 17, lines 34-40, "The present invention may be used in cases of multiple trauma with *long bone fractures*. To realign the bone and minimize blood loss, the trauma surgeon uses an external fixator to quickly stabilize the patient. Thereafter, the surgeon may take *a fluoroscopic or other image of the fractures* and apply the present system to obtain an exact realignment of the fractured bone." In other words, Krause et al. not only expressly disclose that "the present invention may be used in cases of multiple traumas with *long bone fractures*." But also expressly

disclose that "the surgeon may take *a fluoroscopic or other image of the fractures* and apply the present system to obtain an exact realignment of the fractured bone." Therefore, Applicants' argument that "fractures are not visually accessible, and are not even imaged by Krause to make them artificially visually accessible" is not persuasive.

Conclusion

10. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Herng-der Day whose telephone number is (571) 272-3777. The Examiner can normally be reached on 9:00 - 17:30.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: (571) 272-2100.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kamini S. Shah can be reached on (571) 272-2279. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kamini S Shah/

Supervisory Patent Examiner, Art Unit 2128

/Herng-der Day/
Examiner, Art Unit 2128

June 25, 2009